UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,014	09/13/1999	VANESSA HSEI	P1085R3	5890

7590 09/10/2002

Ginger R. Dreger
Knobbe, Martens, Olson & Bear, LLP
620 Newport Center Drive Sixteenth Floor
Newport Beach, CA 92660

EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	20

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/355,014	Applicant(s) HSEI ET AL.	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2002* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-13 and 15-52* is/are pending in the application.

4a) Of the above claim(s) *35-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-13 and 15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. The request filed on 6/11/02 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/355014 is acceptable and a RCE has been established. Claims 1-4, 6-13, 15-52 are pending and claims 1-4, 6-13, 15-34 are currently under prosecution. An action on the RCE follows.

2. Claims 1-4, 6-13, 15-52 are pending.

Claims 5 and 14 were canceled in the amendment filed 1/11/02.

Claims 1 and 6 were amended in the amendment filed 1/11/02.

Claims 1-4, 6-13, 15-34 are under examination.

3 Claims 35-52 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made without traverse in Paper No. 7.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Information Disclosure Statement

5. The examiner acknowledges the 1449 from application 09/121,952, however, 09/121952 was not available for inspection and also the references filed 3/8/01 were also not located. The examiner apologizes for any inconvenience but requests that

copies of the references numbered 23-109 be resubmitted All patent applications listed have been considered. LRH

Rejections Withdrawn

6. The rejection of claims 1, 10-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 7, 19, 26-27 of copending Application No. 09/234,182 is withdrawn.

7. The rejection of claims 1, 13, 18-22, and 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) is withdrawn in view of the amendments to the claims.

Response to Arguments

8. The rejection of claims 1-4, 6-13, 15-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 09/489,394 is maintained.

The response filed 10/3/016/11/02 did not address this rejection. The response filed 1/11/02 states that "the Examiner should find all claims pending allowable. Accordingly, the proper procedure would be to withdraw the obvious-type double patenting rejections in the present application". In response to this argument, the claims are not in condition for allowance and the rejection is maintained.

9. The rejection of claims 1-4, 6-13, 15-16, 18-24, 28-34 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) is maintained.

The responses filed 6/11/02 and 1/11/02 have been carefully considured but is deemed not to be persuasive. The response of 6/11/02 does not address this rejection directly but addresses it in the context of Zapata which was used in the rejection discussed below. The response filed 1/11/02 was addressed in the advisory action but will be addressed again. The response states that Faanes et al is concerned with conjugates to complete antibodies as opposed to antibody fragments and Fannes et al does not teach conjugates with an apparent size of at least 500 kD and the apparent size recited in claim 1 (see page 3 of 1/11/02 response). In response to these arguments, Faanes et al clearly teaches fragments of antibodies (see column 10, lines 8-13) and Faanes et al teach conjugates with an apparent molecular weight of 540 kD (see column 19, lines 23-41). It would be obvious that when using higher molecular weight PEG, as Faanes teaches, the apparent size of the conjugate would be increased accordingly (see column 19, lines 23-41) when higher MW PEG was added thus leading to at least 8-25 fold greater apparent size compared to the antibody fragment.

The fact remains that it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a conjugate consisting of PEG molecules attached to the antibody at various amounts with various molecular weight PEG molecules as taught by Faanes et al.

10. The rejection of claims 1-4, 6-13, 15-25, 28-34 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) and further in view of Zapata et al (FASEB J. 9:A1476, 1995) is maintained.

The responses filed 6/11/02 and 1/11/02 have been carefully considured but is deemed not to be persuasive. The response filed 1/11/02 was addressed in the advisory action but will briefly be addressed again. The response states that while Zapata et al suggests that decrease in serum clearance can be obtained by increasing the molecular weight of PEG in the conjugates, it has no teachings or suggestions that the ratio of PEG-antibody to antibody should be kept within certain limits. In response to this argument, Zapata et al (FASEB J 9;A1476, 1995) also teach reduced clearance and a 10kD PEG worked better that the 5kD PEG, therefore it would be obvious to use a higher MW PEG and as such in view of Faanes et al which teaches 40Kd one skiil in the art would use a higher MW to get better clearance and as such this would increase the apparent MW of the conjugate and the ratio of antibody fragment-PEG to antibody fragment to those recited in the claims.

The response filed 6/11/02 states that although Faanes et al does teach the use of both 5 kD and 40 kD PEG molecules, they refer to the 5 kD molecules as "preferred" and as such Faanes teach a low molecular weight PEG is more preferred. In addition the response states that Zapata et al teach a higher molecular weight PEG is more preferred. Thus, the response concludes that Faanes et al and Zapata et al have exactly opposite teachings and the combination would produce a "seemingly inoperative

device" (see page 2 of response). In response to these arguments, Faanes et al clearly teaches mPEG of up to 40 kD may alternatively be employed (see column 12, lines 61-63) and in view of Zapata et al's teaching that a higher molecular weight (as admitted by applicants) led to extended serum half life, therefore it would be obvious to use a higher MW PEG and as such in view of Faanes et al which teaches 40Kd one skiil in the art would use a higher MW to get reduced clearance and as such this would increase the apparent MW of the conjugate and the ratio to those recited in the claims.

11. The rejection of claims 1 and 33-34 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al (U.S. Patent 5,695,760, filed 4/24/95) and further in view of Harlow et al (Antibodies A Laboratory Manual, Cold Spring Harbor Laboratories, pp 324-339, 1988) is maintained.

The responses filed 6/11/02 and 1/11/02 have been carefully considured but is deemed not to be persuasive. The response filed 1/11/02 states that there is nothing in Harlow et al that would supply the teachings missing from Faanes et al. In response to this argument, Faanes et al has been described above and Harlow clearly teaches non-proteinaceous labels such as 125I, which would be obvious to conjugate to antibodies for detection. The response file 6/11/02 did not address this rejection.

12. The rejection of claims 1, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Faanes et al as applied to claim 1 above and further in view of Doerschuk et al (WO 95/23865, 9/8/95) is maintained.

The responses filed 6/11/02 and 1/11/02 have been carefully considured but is deemed not to be persuasive. The response filed 1/11/02 states that there is nothing in

Doerschuk et al that would supply the teachings missing from Faanes et al. In response to this argument, the Faanes et al reference has been discussed and Doerschuk clearly teaches the IL-8 antibody which could obviously be used for conjugates of Faanes et al.

Conclusions

13. No Claims are allowed.

14. This is a RCE of applicant's earlier Application No. 09/355014. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

SHEELA HUFF
PRIMARY EXAMINER